55. (Amended) An enteral anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing composition, comprising

a first component comprising an active ingredient to be absorbed through the small intestine;

a second component comprising a carrier dispersible form of an active lipid selected from the group consisting of

(A) saturated and unsaturated fats;

(B) fully hydrolyzed fats;

(C) pharmaceutically acceptable salts of any of (A) or (B); and

(D) a mixture of any of (A), (B), or (C);

and

an enteric coating which releases the first and the second components into the proximal segment of the small intestine, where the lipid slows transit and increases digestion, dissolution and/or residence time in, and absorption through, the small intestine without significant degradation and, thereby, increases absorption of the active ingredient thereof through in the presence of the active lipid than in its absence.

REMARKS

The Pending Claims:

Claims 1-95 are pending in this application. The application contains claims related to methods and compositions. With respect to claims directed to methods, Claims 1-20 are directed to a method for prolonging the residence time of an orally or enterally administered substance by promoting its dissolution, bioavailability and/or absorption in the small intestine. Claims 21-23 relate to a method of treating a gastrointestinal disorder by slowing the gastrointestinal transit of an orally or enterally administered substance in a subject. Claim 24 is directed to a method of enhancing the digestion and absorption of orally or enterally administered nutrients and/or pharmacological agents. Claims 25 and 43-44 are directed to a method for reducing diarrhea. Claims 26-27 and 45-47 relate to a method of reducing the serum level of

atherogenic lipids derived from an ingested substance. Claims 28-31 and 48-52 are directed to a method of enhancing the bioavailability of an orally ingested pharmacological agent by promoting a digestive, dissolving, absorptive, anti-atherogenic, anti-diarrheal and/or gastrointestinal transit slowing effect. Claim 34 relates to a method of enhancing the absorption of a substance in the small intestine and promoting anti-atherogenesis, anti-diarrheal, digestion, and/or dissolution, and/or slowing gastrointestinal transit. Claims 35-36 and 53-54 are directed to method of enhancing the absorption of an orally administered substance and promoting an anti-atherogenic and/or anti-diarrheal effect, and promoting digestion and dissolution, and slowing gastrointestinal transit. Claim 37-40 are directed to a method of treating a gastrointestinal disorder by slowing the gastrointestinal transit of an orally administered substance in a subject. Claims 41-42 are directed to a method of enhancing the digestion and absorption of orally administered nutrients and/or pharmacological agents. Claims 87-89 relate to a method of prolonging small intestine transit time while promoting an anti-atherogenic and/or anti-diarrheal effect and/or promoting digestion, dissolution and/or absorption. Claims 90-95 are directed to a method of treating a nutritional deficiency.

With respect to compositions of matter, Claim 32 is directed to an anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing controlled release oral composition. Claim 33 is directed to an anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing liquid enteral composition. Claims 55-60, and 73-86 relate to an enteral anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing composition. Claims 61-63 relate to a lipid dispersion, emulsion or suspension. Claim 64 relates to an emulsion, and Claim 65 to a cellulose emulsion. Claims 66-67 are directed to an oral formulation; Claims 68 and 82 are directed to a controlled release formulation; Claims

69 and 83 relate to a slow release formulation. Claims 70-71 are related to a liquid enteric formulation.

Applicant's Amendments to the Claims

The amendments to Claims 13-16, 19, and 20, in which the dependency is changed from Claim 1 to Claim 12, are to correct obvious typographical errors.

The amendment to Claim 21, line 7, correcting "subject=s" to --subject's--, is also to correct an obvious typographical error.

The amendment to Claim 55, inserting --and-- after line 9, is also to correct a typographical error.

The Office Action and Applicant's Request for Reconsideration and Withdrawal of the Restriction Requirement

The Examiner required restriction, under 35 U.S.C. § 121, and required Applicant to elect a single invention to which the claims must be restricted.

The Examiner presented the following two groups:

1. Group I; Claims 1-20, 24, 28-31, 34-36, 41, 42, 53-95, which the Examiner alleged were drawn to a composition comprising drug, lipid, and carrier.

2. Group II; Claims 21-23, 25-27, 32, 33, 37-40, and 43-52, which the Examiner alleged were drawn to a composition comprising carrier and lipid.

Applicant strongly traverses the restriction requirement, but as required by 37 C.F.R. § 1.143, provisionally elects **Group I**.

Applicant respectfully requests the Examiner to reconsider and withdraw the requirement, because the restriction requirement was based on an arbitrary

mischaracterization of the claims.

First, the Examiner has characterized Group I and Group II claims as being drawn to compositions. But this ignores the fact that both groups conatin both composition and *method* claims.

Second and more importantly, the distinction of Group I from Group II based on whether a recited composition contains a "drug" as well as a carrier and active lipid is both inappropriate and arbitrarily applied to the instant claims. For example, Claims 1-20 of Group I are directed to a method for prolonging the residence time of an orally or enterally administered substance by promoting its dissolution, bioavailability and/or absorption in the small intestine. In particular, independent Claim 1 recites:

> 1. A method for prolonging the residence time of an orally or enterally administered *substance* by promoting its dissolution, bioavailability and/or absorption in the small intestine, comprising ***administering*** to a subject in need of the treatment at least one dose of an anti-atherogenic, anti-diarrheal, digestion, dissolution, absorption promoting and/or gastrointestinal transit slowing ***composition comprising a carrier and a dispersion consisting essentially of an active lipid in the carrier***, the active lipid being selected from the group consisting of saturated and unsaturated fatty acids, fully hydrolyzed fats and mixtures thereof, in an amount of about 0.5 to about 25 grams per dose and in a form effective to promote contact of the lipid with the subject's small intestine and, thereby prolong the residence time of an orally or enterally administered *substance* in the small intestine for a period of time effective to increase dissolution, bioavailability, and/or absorption of the substance therethrough. (Emphasis added)

Note that the claim involves administering a "composition comprising *a carrier and a dispersion consisting essentially of an active lipid in the carrier*." Similar wording describing the administered composition is recited, for example, in independent Claims 12, 24, 28, and 41, which were assigned to Group I by the Examiner. Thus, contrary to the Examiner's characterization, a "drug" is not a necessary constituent of the administered composition in Group I Claims 1-20, 24, 28-31, and 41-42.

Moreover, the wording used in these Group I claims to describe a

composition is significantly indistinguishable from the recitations of claims assigned to Group II by the Examiner, which also do not necessarily contain a "drug". For example independent Claim 21 recites:

> 21. A method of treating a gastrointestinal disorder by slowing the gastrointestinal transit of an orally or enterally administered substance in a subject, comprising ***administering*** to a subject in need of the treatment at least one dose of ***a composition comprising a carrier and a dispersion consisting essentially of an active lipid in the carrier***, the active lipid being selected from the group consisting of saturated and unsaturated fatty acids, fully hydrolyzed fats and mixtures thereof, in an amount of about 0.5 to about 25 grams per dose and in a form effective to promote contact of the lipid with the subject's small intestine and, thereby, slow the gastrointestinal transit of an orally or enterally administered substance through the small intestine. (Emphasis added).

Similarly, independent Claims 37 and 48 recite the step of "administering to a subject . . . a *composition comprising a carrier and a dispersion consisting essentially of an active lipid in the carrier* . . ." Independent Claims 25, 26, 43, and 45 recite the step of administering . . . a composition comprising an active lipid . . . ," which is not limited to a composition containing a carrier. Thus, Group II method Claims 21-23, 25-27, 37-40, 43, 44, and 45-52 describe a composition in terms similar to those used in Group I Claims 1-20, 24, 28-31, and 41-42. This being so, the restriction requirement distinguishing Group I claims from Group II claims is clearly arbitrary and improper.

In addition, method Claim 34 of Group I recites the "composition of claim 33," but Claim 33 is arbitrarily assigned to Group II by the Examiner. Claim 33 is directed to a "composition, comprising a liquid carrier and a dispersion in the carrier consisting essentially of a substance and an active lipid . . ." It should also be noted that, while here a "substance" is included in the composition, the "substance" is by no means limited to a "drug." For example, the specification discloses, at page 9, lines 22-26, that "'substance' encompasses the lumenal content of the gastrointestinal tract which includes, for example, digested and partially digested foods and nutrients, dissolved and/or solubilized pharmacologically active agents as well as incompletely dissolved

and/or solubilized forms thereof, electrolyte-containing lumenal fluids, and the like."

Claim 35, which was assigned to Group I, is directed to method of enhancing the absorption of an orally administered substance and promoting an anti-atherogenic and/or anti-diarrheal effect, and promoting digestion and dissolution, and slowing gastrointestinal transit, which method involves "administering to a subject a . . . composition, comprising a core comprising a *substance* selected from the group consisting of *nutrients* and *pharmacological agents* and a coating thereon comprising an active lipid." Thus, Claim 35 and Claim 36, dependent therefrom, do not describe a composition limited to one comprising a "drug, lipid, and carrier," as characterized by the arbitrary Group I characteristics.

The same can be said for the remaining independent claims of Group I, such as Claim 53, directed to a method that involves administering to a subject . . . [a] composition configured in a coated or uncoated tablet, capsule, or caplet form, comprising a core comprising a *substance* selected from the group consisting of *nutrients* and *pharmacological agents* and a coating thereon comprising an active lipid . . ." (Emphasis added). Also, independent Claims 55 and 73 are directed to a ". . . composition, comprising a *first component comprising an active ingredient* to be absorbed through the [stomach or] small intestine; a second component comprising . . . a carrier dispersible form of an active lipid . . ." (Emphasis added). As taught in dependent Claims 56-58 and 76-78, as filed, the "active ingredient" includes nutrients (e.g., foodstuffs, vitamins and minerals) and/or a host of various pharmacological agents. Thus, Claims 53-54 and 55-95 (including claims directly or indirectly dependent from Claims 55 and 73), do not teach a composition limited to one comprising a "drug, lipid, and carrier," as the Examiner has characterized Group I.

Since the distinctions between Group I and Group II, as asserted by the Examiner, are arbitrary and are arbitrarily applied to the instant claims, the restriction requirement is improper. Consequently, Applicant respectfully requests the Examiner

to withdraw the requirement.

Examiner's Requirement of an Election of Species and Applicant's Response

The Examiner required elections of species, under 35 U.S.C. § 121. The Examiner presented the following species of the claimed invention for election:

(a) coated microspheres or particles;

(b) uncoated microspheres or particles;

(c) dispersible powder or granule formulation;

(d) suspension;

(e) emulsion;

(f) solution;

(g) syrup;

(h) elixir;

(i) coated tablet;

(j) uncoated tablet;

(k) troche;

(l) hard capsule;

(m) soft capsule;

(n) lozenge;

(o) aqueous suspension;

(p) oily suspension; and

(q) caplet.

Applicant elects: **(a) coated microspheres or particles**

Applicant's election is made with a complete reservation of all rights under 35 U.S.C. § 121.

The Examiner stated that currently Claims 1 and 21 are generic. Applicant respectfully submits that additional claims, including Claims 2-20, 22-60, 66, 70-80, and 84-95 are also generic.

Respectfully submitted,

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